K031474

OCT 15 2003

Summary of Safety and Effectiveness
for the
SC Total Hip System

This safety and effectiveness summary for the SC Total Hip System is provided as required per Section 513(i)(3) of the Food, Drug and Cosmetic Act.

1. Submitter :
Orthopedic Alliance LLC
41558 Eastman Drive
Suite A
Marietta, CA 92562

Contact Person :
Roger Williams
Orthopedic Alliance LLC
41558 Eastman Drive
Suite A
Marietta, CA 92562
Telephone: (909) 304-9001

Date Prepared: May 3, 2003

2. Tradename: SC Total Hip System
Common Name: Total Hip System
Classification Name: Hip joint metal /polymer semi-constrained cemented prosthesis (888.3350)

3. Predicate or legally marketed devices which are substantially equivalent :

- SL-Plus Hip Stem (Plus Orthopedics)
- Zweymuller SL Hip System (AlloPro)
- Lester Press Fit Hip System (Kirschner)
- Alloclassic Zweymuller SL Hip Stem (Sulzer Medica)

4. Description of the device :

The SC Total Hip System is a total hip system used for the replacement of severely disabled hip joints. It consists of femoral stems, modular femoral heads and acetabular components. The femoral stems are straight, non-porous collarless designs in standard and lateralized configurations. Revision lengths are also available. The acetabular components are UHMWPE, in various diameters, with various offset options.

Materials: The devices are manufactured from Ti6Al-7Nb Titanium alloy, CoCrMo alloy and Ultra High Molecular Weight Polyethylene (UHMWPE) per ASTM and ISO standards.

Function: The system functions to provide pain relief and improved function to the hip that has been disabled from arthritic conditions or trauma.

5. Intended Use:

The SC Total Hip System is indicated for use in the treatment of severely disabled hip joints resulting from painful osteo-, rheumatoid, and post-traumatic arthritis, and the late stages of avascular necrosis, and for the revision of previous hip surgeries.
The SC Femoral Hip Stem is indicated for use with or without bone cement. The SC Acetabular Cup is for use with bone cement only.

6. Comparison of the technological characteristics of the device to predicate and legally marketed devices :

There are no significant differences between the SC Total Hip System and other total hip systems currently being marketed which would adversely affect the use of the product. It is substantially equivalent to these other devices in design, function, materials and intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 15 2003

Mr. Roger Williams
Orthopedic Alliance LLC
41558 Eastman Drive, Suite A
Marietta, CA 92562

Re: K031474
Trade/Device Name: SC Total Hip System
Regulation Number: 21 CFR 888.3350
Regulation Name: Hip joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: JDI, LWJ
Dated: September 17, 2003
Received: September 22, 2003

Dear Mr. Williams:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for

Celia Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known) : K031474

Device Name : SC Total Hip System

Indications For Use :

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The SC Femoral Hip Stem is indicated for use with or without bone cement.

The SC Acetabular Cup is for use with bone cement only.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription use ___ OR Over-the-counter use _____
(PER 21 CFR 801.109)

(optional format 1-2-96)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K031474 MNA